REMARKS

Claim Amendments

Claims 5, 7, 16, 18, 51, 53, 56 and 58 have been amended and Claims 6, 17, 52 and 57 have been canceled and Claims 62-65 have been added herein. Support for the amendments can be found throughout the specification and in the claims as originally filed. No new matter has been added.

Claim Objections

The claims were objected to as containing non-elected subject matter. As stated above, Claims 5, 7, 16, 18, 51, 53, 56 and 58 have been amended to remove any reference to the non-elected matter. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 51-55 Under 35 U.S.C. §112, First Paragraph

Claims 51-55 have been rejected under 35 U.S.C. §112, first paragraph, because, according to the Office Action, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims. Particularly, the Office asserted that while the specification enables using the compounds of formula (II) for inhibiting bacterial growth, the specification does not enable the use of said compounds for inhibiting something other than bacterial growth, i.e., heart disease. For the following reasons, the applicants respectfully traverse.

First, the Applicants note that claims 51-55 are directed to a method for inhibiting ß-lactamase activity. The Office has not alleged that the application does not provide written description support for using the compounds of the invention to inhibit ß-lactamase activity, nor that the specification does not enable using the compounds of the invention to inhibit ß-lactamase activity. As such claim 51-55 meet the requirements of 35 U.S.C. § 112. Therefore, the claimed invention has utility and the specification is enabled for this utility. Of great concern to the Applicants is that the Office is unilaterally determining that the claimed invention lacks a utility that they agree with and is hiding this judgment under the guise of an enablement rejection.

Applicants submit that the specification describes the claimed invention in such terms as to enable a skilled artisan to make and use the full scope of the claimed invention without undue

experimentation. A specification is presumed to be enabling, and the burden is on the Office to provide evidence or scientific reasoning to the contrary to support an assertion to the contrary. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

It has been consistently held that for enablement the specification need teach only one mode of making and using a claimed composition. see *Cellpro,* 152 F.3d at 1361 (affirming summary judgment of enablement of a product claim over a challenge that two alternative embodiments disclosed in the patent were not enabled because 'the enablement requirement is met if the description enables any mode of making and using the invention')." *See Johns Hopkins Univ. v. Cellpro, Inc.,* 152 F.3d 1342, 1361 (Fed. Cir. 1998); *Engel Indus. Inc. v. Lockformer Co.,* 946 F.2d 1528, 1533 (Fed. Cir. 1991) . . [T]here is no requirement that the specification enable every mode for making and using the claimed products."; "The reason for such a rule is clear. What would be the value in patenting a composition at all if, by making the slightest alteration in the method of making what is nonetheless the same product, a competitor were able to evade liability? A patent system that permitted such conduct would remove the carrot dangling in front of the inventor's nose. If inventors were so easily divested of their limited monopoly rights attendant to their novel, useful, and nonobvious contributions, they would likely abandon their pursuits and thereby inhibit progress. The law does not permit such an outcome.").

The Office Action is basing the enablement of the claimed invention, not on what is being claimed, but upon a list of possible downstream consequences of what is being claimed. However all of this disregards the teaching of the specification about ß-lactamase inhibitors and methods of inhibiting ß-lactamase with said inhibitors. The downstream consequences of these methods may influence the commercial success of the compounds, however, this does not affect whether or not the methods are enabled for their claimed purpose. Not every **possible** embodiment of a claim need be enabled (See *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291, 6 USPQ2d 1065, 1073-74 (D. Del. 1987), aff'd 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989) "it is the claimed invention for which enablement is required; A patent applicant is not required ... to predict every possible variation, improvement or commercial embodiment of his invention."). Rather, does the specification teach one skilled in the art to practice the claimed invention (i.e., to inhibit ß-lactamase activity using the compounds disclosed therein)?

As stated above, Claims 51-55 are directed towards methods of inhibiting ß-lactamase activity by administering the **inhibitors** of ß-lactamase according to formula (II). The compositions have been found to be enabled; therefore, methods of using the compositions for their purpose (i.e., using inhibitors of ß-lactamase to inhibit ß-lactamase activity) are also enabled. Although the claimed compositions may have other uses, Applicants are not required to specifically enable every possible use for the compound and, in fact, need not describe actual embodiments or examples. Indeed, Applicants need not have reduced the invention to practice prior to filing. An enabling *disclosure* is all that is required.

The Office further alleged that Applicants have not provided evidence that the tests in the specification predict using the claimed compounds for treating any diseases other than inhibiting bacterial growth. In doing so, the Office is reading limitations into the claims that simply are not there. Whether or not inhibition of ß-lactamase activity results in a therapeutic treatment such inhibition is still useful. For example, it would be evident to one skilled in the art that inhibition of ß-lactamase activity that does not produce a therapeutic effect is a useful tool for probing the role of ß-lactamases. Of course, if demonstrated inhibition of ß-lactamase activity **did** correspond to a therapeutic benefit that would obviously also be useful. Either way, inhibition of ß-lactamase activity using the compounds of the claims is a useful invention which is enabled by the specification. The Office has provided no evidence or other reason to doubt that the compounds in claims 51-55 would inhibit ß-lactamase, or that such inhibition would be measurable or would provide useful information.

Since inhibition of ß-lactamase is a useful invention, whether or not it provides a therapeutic benefit, and since such inhibition is fully enabled by the Specification, Applicants respectfully request that the rejection of claims 51-55 be withdrawn.

The Office further asserted that because the specification does not sufficiently enable a skilled artisan, undue experimentation is needed to determine what diseases would be benefited by administration of the instantly claimed compounds. The Office considered factors such as the nature of the invention, state of the prior art, predictability or lack thereof in the art, the amount of guidance, working examples in the specification, breadth of the claims, and quantity of experimentation as further indication that one skilled in the art would have to do undue experimentation. Again, the Office is reading limitations into the claims which do not exist. As discussed above, inhibition of ß-lactamase is useful whether or not a therapeutic benefit is

achieved. Thus, the enablement question is properly limited to whether the claimed compounds inhibit ß-lactamase activity, and whether such inhibition can be ascertained.

With this in mind, Applicants disagree with the Office that undue experimentation is needed. The law clearly states that "a considerable amount of experimentation is permissible, if it is merely routine." *In re Wands,* 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Further, the fact that experimentation may be complex does not necessarily make it undue. *Massachusetts Institute of Technology v. A.B. Fortia,* 774 F.2d 1104 (Fed. Cir. 1985); *In re Wands,* 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Thus, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498 (CCPA 1976).

The claims are directed to inhibiting ß-lactamase activity. As discussed above, the specification together with the well-known knowledge in the art provides sufficient guidance to enable skilled artisans to produce the compounds of the invention and use the compounds for inhibiting ß-lactamase, regardless of the downstream consequence. The specification describes how to make the compounds and use them for inhibiting ß-lactamase activity. Any additional experimentation that may be needed is merely routine, using disclosed and well-established and standard synthetic techniques, screening and testing procedures.

With regard to the Wands factors discussed in the Office Action, the foregoing discussion demonstrates that when considering the factors in their totality, Claims 51-55 are enabled. Reconsideration and withdrawal of the rejection are respectfully requested.

Allowable Subject Matter

Applicants acknowledge that Claim 22 was found to be neither anticipated nor rendered obvious over the art of record, and therefore allowable.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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